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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,677	10/28/2005	Leena Otsomaa	06267.0130	8394

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EXAMINER	
ROBINSON, BINTA M	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
07/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,677	OTSOMAA ET AL.	
	Examiner	Art Unit	
	Binta M. Robinson	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7/8/05* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/23/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The 103 (a) rejection over Koskelainen et. al. and the 112, first paragraph enablement rejection of claims 7 and 9 are withdrawn in light of applicant's remarks filed 3/28/07. The obvious double patenting rejection is dropped over claims 7 and 9 in light of these claims cancellation.

(modified old rejections)

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 8, 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10482396 (PGPub 20040235905). Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims a genus of compounds, pharmaceutical

compositions, and methods of treating which overlap in subject matter with the instant genus of compounds, pharmaceutical compositions and methods of treating.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Application 10482396 teaches the instant compound as shown in Formula I, wherein X is O, CH2, or –C(O)-, Z is –CHR9 or valence bond, Y is –CH2, -C(O)-, CH(OR10), O, S, provided that in case Z is a valence bond, Y is not C(O); the dashed line represents an optional double bond in which case Z is –CR9 and Y is –CH-, C(OR10)-, R1 is pyridinyl(R6), R2 and R3 are independently H, lower alkyl, lower alkoxy, -NO2, halogen, CF3, OH, NHR8, or –COOH, R6 is –NO2, R9 is H or lower alkyl, R10 is H, alkylsulfonyl or acyl, R14 and R19 are independently H, acyl, alkylsulfonyl, C(S)NHR17 or C(O)NHR17, R17 is H or lower alkyl. At claim 1, see pages 88-89. The difference between the prior art genus of compounds, pharmaceutical compositions and methods of treating and the instant genus, pharmaceutical compositions and methods of treating is that the prior art genus overlaps in subject matter with the instant genus of compounds, compositions, and methods of use.

The patentee teaches a very limited number of selections for the variables of this genus that are small enough in number to be combined to form the instant genus. Since the patentee teaches a small group of compounds within a genus that overlaps in subject matter with the instant genus, it would have been obvious for one of ordinary skill in the art to easily envision and test the compounds that

overlap with the prior art genus of compounds. Accordingly, the compounds, compositions, and methods of use of these compounds are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds, compositions and methods of use over those of the generic prior art compounds, compositions and methods of use.

(new rejections)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 8 is rejected as indefinite and unclear because it is directed to a method of inhibiting a mechanism rather than treating a specific host population and treating a particular disease condition, yet the phrase "therapeutically effective" is in the claim. It is unclear if claim 8 is directed to the treatment of a particular disease condition, or to inhibiting a mechanism.

Response to Applicants Remarks

The examiner notes the applicant's request to hold the obvious type double patenting rejection over Koskelainen in abeyance. However, the applicant does not argue this rejection. Therefore, this rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Janet Andres can be reached on 571-272-0867.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.

BMR
June 28, 2007

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER